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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' MEMORANDUM ADDRESSING THE RELEVANCY AND DISCOVERABILITY OF INFORMATION RELATED TO THE FDA INSPECTION AND WARNING LETTER

In accordance with Section V of the Court's February 2, 2016 Case Management Order No. 8 [Dkt. No. 519], Defendants C. R. Bard, Inc. ("C. R. Bard") and Bard Peripheral Vascular, Inc. ("BPV") (C. R. Bard and BPV are collectively referred to as "Bard") hereby submit this memorandum that addresses the relevancy and discoverability of information related to the FDA inspection and Warning Letter.

The FDA inspection and Warning Letter (the "Warning Letter") is a red herring in this litigation. While the Plaintiffs seek to use the Warning Letter as a subterfuge to somehow justify expansive new discovery, the reality is that the Warning Letter has little,

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if any, relevance to the issues at stake in the Bard IVC Filter Litigation. For instance, while the Warning Letter includes issues related to the Recovery® Cone, not a single plaintiff in this MDL alleges an injury attributable to that device. Similarly, while the Warning Letter includes issues related to Bard's complaint handling and MDR reporting, the vast majority of those issues do not involve a failure to report an event to the FDA, only how the company characterized the event or documented its internal files. Nor do those complaint handling issues alter or affect Bard's internal complaint trending or adverse event rate information.

Bard has already provided the Plaintiffs with substantial discovery regarding the Warning Letter, including all of Bard's communications with the FDA regarding the letter. Bard has also provided the Plaintiffs with 10 hours of 30(b)(6) deposition testimony by Mr. Chad Modra, who is the witness with the most knowledge and information regarding the Warning Letter. Simply put, additional discovery regarding the Warning Letter is not warranted.

I. INTRODUCTION

A. The FDA Warning Letter

On July 13, 2015, the FDA issued a Warning Letter to Bard, following FDA's inspections of Bard's facilities in New York and Arizona, and FDA's subsequent Form 483 Letters. *See* July 13, 2015 FDA Warning Letter attached as Exhibit "A." The Warning Letter can be broken down into the following four categories: (i) issues regarding the regulatory categorization of the Recovery® Cone (Warning Letter Item Nos. 1 and 2)[1]; (ii) issues regarding Bard's complaint handling and medical device reporting ("MDR") (Warning Letter Item Nos. 3, 7, and 8); (iii) issues regarding Bard's manufacturing

[1] The FDA took the position in the Warning Letter that the Recovery® Cone should have been classified as a Class II medical device requiring a 510(k) submission and clearance before being marketed. The FDA took this position even though Bard told the FDA in 2003 that Bard classified the Recovery® Cone as a Class I device, which does not require a 510(k) or clearance, and even though FDA was aware that Bard has been marketing the Recovery® Cone for more than 12 years. In response to the Warning Letter, Bard promptly submitted a 510(k) submission for the Recovery® Cone on July 30, 2015.

processes for the Denali® Filter (Warning Letter Item Nos. 4(b), 5, and 6); and (iv) issues regarding the cleaning process of the Simon Nitinol, Eclipse®, and Denali® Filters (Warning Letter Item No. 4(a)). Although the Warning Letter addresses these four categories, the Plaintiffs have focused their time, attention, and arguments almost exclusively on categories (i) and (ii). *See, e.g.*, Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at pp. 29-32 (stating the Plaintiffs' position regarding whether additional discovery relating to the Warning Letter is needed). Indeed, aside from reading or paraphrasing Warning Letter Item numbers 4, 5, and 6 in the record (categories (iii) and (iv) above), the Plaintiffs did not question Mr. Modra on these topics in his deposition. *See* December 12, 2015, Deposition of Chad Modra ("Modra Dep. Vol. I"), relevant excerpts of which are attached as Exhibit "B," at 337:24 – 339:21.

II. ARGUMENT AND CITATION TO AUTHORITIES

A. Discovery Regarding the Warning Letter Needs to be Relevant and Proportional to the Needs of the Case

Under the recently amended Rule 26(b)(1) of the Federal Rules of Civil Procedure, all requested discovery must be relevant ***and*** proportional to the needs of the case. Rule 26(b)(1) defines the scope of discovery as follows:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. Proc. 26(b)(1).

The amendment to Rule 26(b)(1) reflects the Advisory Committee's belief that "an increased emphasis on proportionality" would aid in achieving Rule 1's goal "to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. Proc. 1; *see* June 14, 2014 Memorandum from the Committee on Rules of Practice and Procedure of the Judicial Conference of the United States to Judge Jeffrey Sutton,

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Chair, Standing Committee on Rules of Practice and Procedure, at p. B-6, available at http://www.uscourts.gov/file/18218/download ("[A] principal conclusion of the Duke Conference was that discovery in civil litigation would more often achieve the goals of Rule 1 through an increased emphasis on proportionality.").

B. Bard Has Provided the Plaintiffs With Substantial Discovery Regarding the Warning Letter

The voluminous documents and deposition testimony provided by Bard to the Plaintiffs regarding the Warning Letter are more than sufficient for this litigation. Initially, Bard notes that, in accordance with the Court's October 30, 2015 Case Management Order No. 2, on November 10, 2015, Bard produced "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." Case Mgmt. Order No. 2 [Dkt. No. 249] at p. 3. These documents identified by Bard's counsel included all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." [2] Case Mgmt. Conf. Tr. [Dkt. No. 277] at 120:7-10 (Oct. 29, 2015). Bard supplemented its production of Warning Letter communications on several occasions to furnish the Plaintiffs with later communications with the FDA. In total, Bard produced to

[2] The Plaintiffs have erroneously argued that Bard "refused" to produce certain documents in response to the Plaintiffs' Notice of Deposition and accompanying requests for production of documents. *See* Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 31 (arguing that Bard "refused" to produce certain documents in advance of Mr. Modra's deposition). The Plaintiffs' document requests, which were the subject of extensive argument at the first MDL conference, sought documents far beyond the scope of materials ultimately authorized and ordered by this Court in its Case Management Order No. 2. For example, during that conference, the Plaintiffs asked for all of Bard's internal communications regarding the Warning Letter. *See* Case Mgmt. Conf. Tr. [Dkt. No. 277] at 122:4 - 123:18 (Oct. 29, 2015). However, the Court limited the scope of Bard's required production to "the documents described by defense counsel," which were Bard's communications with the FDA regarding the Warning Letter. *See* Case Mgmt. Order No. 2 [Dkt. No. 249] at p. 3. The Plaintiffs have nonetheless requested again "all internal communications relating to the subject matter of the warning letter issued by FDA on July 13, 2015." *See* Pls.' Notice of Deposition and Related Requests for Production of Documents [Dkt. No. 451-1] at p. 6. Based on the Court's Case Management Order No. 2, Bard objected to producing documents beyond its communications with the FDA regarding the Warning Letter. *See* Bard's Responses and Objections to Plaintiff's Notice of Deposition and Related Requests for Production of Documents, attached as Exhibit "C."

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the Plaintiffs over 13,000 pages of communications and documents between Bard and the FDA regarding the Warning Letter. These documents include (a) all of the FDA's correspondence to Bard regarding the Warning Letter; (b) Bard's "official" response letters to the FDA; (c) all attachments to those response letters (which include voluminous internal documents reflecting the actions that Bard took in response to the FDA's 483 Letters and Warning Letter); (d) Bard's 510(k) submission for the Recovery® Cone; (e) Bard's communications with the FDA regarding that 510(k) submission; and (f) various e-mail communications with the FDA regarding the Warning Letter and Recovery® Cone 510(k) submission. *See* Index of FDA Warning Letter and 483 Letter Communications produced to the Plaintiffs, attached as Exhibit "D." These voluminous documents are more than adequate to provide the Plaintiffs with all necessary information concerning the issues identified by the FDA in the Warning Letter, the actions that Bard took in response to the Warning Letter, and FDA's responses and follow-up regarding those actions taken in response to the Warning Letter. Nonetheless, the Plaintiffs have served still another set of document requests recently, seeking virtually every shred of paper and every internal e-mail that even mentions the Warning Letter. *See* Plaintiffs' Second Set of Requests for Production of Documents [Dkt. No. 451-2].

Bard also produced for deposition Mr. Chad Modra, who was Bard's 30(b)(6) witness regarding the Warning Letter. Mr. Modra is BPV's Vice President of Quality. He provided the Plaintiffs with 10 hours of deposition testimony regarding the Warning Letter. [3] Mr. Modra's testimony readily demonstrates that he is the single most knowledgeable person at Bard regarding the Warning Letter. For example, he testified that he was directly involved in drafting all of the correspondence from Bard to the FDA. *See* Ex. B, Modra Dep. Vol. I, at 14:1-9. He was in charge of opening and managing the corrective and preventative actions that were undertaken by Bard in response to the Warning Letter. *See id.* at 134:24-135:20, 261:7-20. He testified that he was involved in

[3] Mr. Modra testified for seven hours on December 15, 2015, and for another three hours on January 20, 2016.

preparing Bard's 510(k) submission for the Recovery® Cone, which was submitted in response to the Warning Letter. *See id.* at 287:6-13. He was also responsible for complaint investigations, complaint trending, and FDA compliance for MDR reporting during the relevant time period, and he was responsible for reporting to the BPV Management Board (of which he was a member during the relevant time period) regarding complaint trending. *See id.* at 84:1-20, 303:9-15, 306:25-307:8.

Given his intimate involvement with the complaint handling and trending practices at BPV, Mr. Modra was involved in managing and overseeing Bard's retrospective complaint handling and MDR reporting analysis (i.e., an internal audit) undertaken in response to the Warning Letter. *See id.* at 87:14-22, 216:3-18. That analysis assessed whether Bard properly characterized its MDRs as "serious injuries" versus "malfunctions." The Plaintiffs questioned Mr. Modra at length regarding that retrospective analysis.[4] That analysis initially concluded that Bard should have reported certain MDRs as "serious injuries" instead of "malfunctions," and Bard revised and submitted supplemental MDRs to the FDA accordingly. However, Bard's later communications with the FDA have clarified that, in submitting those supplemental MDRs to the FDA in an effort to comply with Bard's understanding of the FDA's directives, Bard had actually begun overreporting instances of "serious injury" when they should have been characterized as "malfunctions." *See id.* at 221:18-222:2; 227:17-228:16. Regardless, Mr. Modra's testimony is unequivocally clear that regardless of Bard's characterization of an MDR as a "serious injury" versus a "malfunction," Bard's trending and rate information remains the same. *See id.* at 144:21-145:6; *see also id.* at 165:21-166:8; 203:1-7. This is because Bard's internal trending and rate information does not depend on whether an adverse event is classified as a "serious injury" or a "malfunction." *See id.* at 110:1-10. Mr. Modra testified that he verified the accuracy of Bard's internal trending and

[4] *See, e.g.*, Modra Dep. Vol. I at 164:5-230:25. Because of the length of this excerpt, Bard is not attaching it to this Memorandum. However, should the Court request this excerpt, Bard would be happy to provide it to the Court.

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rate information after the retrospective analysis, concluding that Bard's internal rates for complications such as fracture, migration, tilt, and perforation were not affected by the analysis or change in complaint characterization. *See* January 20, 2016, Deposition of Chad Modra ("Modra Dep. Vol. II"), relevant excerpts of which are attached as Exhibit "E," at 484:24-485:7, 501:19-502:25, 515:8-517:3.

In short, Mr. Modra's testimony made clear that he was the person most knowledgeable regarding the Warning Letter. Ex. B, Modra Dep. Vol. I, at 31:5-14. The Plaintiffs had a full 10 hours to depose Mr. Modra regarding any and all topics related to the Warning Letter. Notwithstanding having almost 50% more time than the normally allotted seven hours of deposition time under Rule 30(d)(1) dedicated to questioning Bard's most knowledgeable witness regarding the Warning Letter, the Plaintiffs nonetheless seek to depose additional individuals regarding the Warning Letter, including Maureen Uebelacker, Judy Ludwig, John Wheeler, Gin Schulz, Mary Edwards, and Rob Carr. The testimony from these individuals would largely be duplicative of the testimony already provided by Mr. Modra. For example, during the relevant time period, Mss. Uebelacker and Ludwig and Mr. Wheeler worked under Mr. Modra's supervision, with Ms. Uebelacker reporting directly to Mr. Modra, and Ms. Ludwig and Mr. Wheeler reporting to Ms. Uebelacker. *See id.* at 17:8-16, 38:23-39:13, 120:2-13. All of Mss. Uebelacker's and Ludwig's and Mr. Wheeler's work related to the Warning Letter and Bard's complaint handling and MDR reporting would have been directed and overseen by Mr. Modra, who had ultimate responsibility for those functions. *See id.* at 84:1-20.

Ms. Schulz was Mr. Modra's immediate boss at the corporate level at C. R. Bard in New Jersey. *See id.* at 17:4-7. While Mr. Modra would provide Ms. Schulz with updates regarding BPV's activities in response to the Warning Letter, she did not have the hands-on involvement regarding Bard's response to the Warning Letter like Mr. Modra did. *See id.* at 162:10-163:8. Indeed, Mr. Modra testified that Ms. Schulz did not have any communications with the FDA regarding the Warning Letter. *Id.* at 287:20-25.

Mr. Carr and Ms. Edwards were involved with the Recovery® Filter and

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Recovery® Cone prior to Bard marketing those devices in 2002 and 2003. Mr. Carr was director of research and development at BPV, and he has been deposed at length numerous times regarding the Recovery® Filter. *See* Bard's Chart of "Prior Depositions" [Dkt. No. 376-2], at pp. 2-3 (demonstrating that Mr. Carr has been deposed 10 times in the Bard IVC Filter Litigation). Ms. Edwards was involved with preparing the regulatory submissions for the Recovery® Filter, but she left Bard 12 years ago. She was deposed by the Plaintiffs' Co-Lead/Liaison Counsel, Mr. Ramon Lopez, in 2014, regarding the Recovery® Filter. *See id.* at 5. Neither Mr. Carr nor Ms. Edwards had any direct involvement in responding to the Warning Letter or overseeing or engaging in actions in response to that letter.

Finally, the Plaintiffs assert that they need to take a 30(b)(6) deposition of Bard regarding "Bard's internal characterization, counting, trending, and reporting of injuries and deaths." Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 32. However, such a deposition would be largely duplicative of depositions already taken in the Bard IVC Filter litigation. In 2013, Mr. Modra testified as Bard's 30(b)(6) witness concerning a variety of post-market surveillance topics. *See* First Amended Notice of Taking Rule 30(b)(6) Deposition: Adverse Events/Post-Marketing Surveillance, served in *Kevin Phillips v. C. R. Bard, Inc., et al.*, Civil Action No. 3:12-cv-00344-RCJ-WGC, formerly pending in the United States District Court for the District of Nevada, attached as Exhibit "F." The topics for which Mr. Modra gave deposition testimony in 2013 include Bard's procedures for MDRs (Topic No. 4), Bard's complaint reports and MDRs (Topic No. 5), Bard's policies regarding the contents, storage, and maintenance of complaint reports and MDRs (Topic No. 6), Bard's policies regarding collecting information about adverse event reports (Topic No. 8), and all of Bard's efforts to track and trend reports of complications with Bard's IVC filters (Topic No. 10). *See id.* More recently, as Bard's 30(b)(6) witness regarding the Warning Letter, Mr. Modra provided substantial testimony regarding Bard's complaint handling, trending, and

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reporting.[5]

This voluminous discovery provided by Bard to the Plaintiffs regarding the Warning Letter is more than adequate for this litigation. It provides the Plaintiffs with all of the key documents, all of the key communications, and the most important witness regarding the Warning Letter. Therefore, additional discovery (either through depositions or through document requests) is not needed and would not be "proportional to the needs of the case," particularly considering "the importance [or lack thereof] of the discovery in resolving the issues" at stake in this litigation. Fed. R. Civ. Proc. 26(b)(1).

C. Issues Related to the Recovery® Cone Are Irrelevant

The Plaintiffs insist that they need expansive new discovery regarding the Recovery® Cone, arguing that evidence regarding the Recovery® Cone "goes to Plaintiffs' failure to warn, misrepresentation, fraud, and punitive damages claims." Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 40. The Plaintiffs' arguments are unfounded.

Initially, Bard cannot stress enough the fact that in 10 years of litigation, ***Bard has never faced a single case alleging injury attributable to the Recovery® Cone***. The Plaintiffs' claims in this litigation turn not on whether the Recovery® Cone is defectively designed or manufactured, or whether Bard provided appropriate warnings regarding that device, but on whether Bard's ***IVC Filters*** are defectively designed or manufactured, and

[5] Indeed, the Plaintiffs spent the majority of their first seven hours of deposition of Mr. Modra asking him questions relating to Bard's complaint handling, trending, and reporting. *See, e.g.*, Modra Dep. Vol. I at 34:9-45:25 (discussing training and specific employees involved with post-market surveillance); 84:1-113:10 (discussing system of reporting complaints to the FDA and substance of specific complaints); 134:6-152:12 (discussing daily field assurance and quality assurance procedures, training, and complaint characterization and determination); 164:5-230:25 (discussing trending, coding, and reporting of complaints generally and as part of retrospective analysis); 231:13-247:17 (discussing complaint handling training program); 248:4-258:15 (questioning related to the Plaintiffs' counsel's statement that "I wanted to make sure that I have a full understanding of this notion of internal trending and event coding"); 258:17-303:17, 316:18-333:8 (discussing corrective action and root cause determination of complaint handling errors). Because of the length of these excerpts, Bard is not attaching them to this Memorandum. However, should the Court request these excerpts, Bard would be happy to provide them to the Court.

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whether Bard provided appropriate warnings regarding Bard's ***IVC Filters***. The technical regulatory status of the Recovery® Cone is simply not relevant to resolving these core issues. *See* Fed. R. Civ. Proc. 26(b)(1) (under proportionality principles, discoverability turns, at least in part, on "the importance of the discovery in resolving the issues" at stake in the litigation). Moreover, although the Plaintiffs suggest that Bard has somehow hid information from the FDA regarding the Recovery® Cone, *see* Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 40, the fact is that from day one, Bard expressly informed the FDA regarding Bard's regulatory characterization of the Recovery® Cone. In the 510(k) for the Recovery® Filter for a retrievable indication in 2003, Bard told the FDA as follows:

> The Recovery Cone is a manual surgical instrument for general use. Title 21 CFR Section 878.4800. Manual surgical instruments are Class I and exempt.

See excerpt from Recovery® Filter 510(k) submission (K031328), attached as Exhibit "G." Additionally, Bard submitted its 2003 510(k) submission for the "Recovery® Filter System," and it included important animal and clinical testing and other information regarding the use of the Recovery® Cone to remove the Recovery® Filter. As such, until the FDA's Warning Letter, Bard considered the Recovery® Cone cleared as part of the "Recovery® Filter System," which was cleared in 2003.

The Plaintiffs argue that if the Recovery® Cone is not "properly authorized . . . every patient faces a significantly more complex removal procedure requiring actual surgery." *See* Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 40. According to the Plaintiffs, this issue "affects literally every plaintiff with a lawsuit in the MDL." *Id.* The Plaintiffs' assertions are not grounded in the facts, and their arguments fail for two reasons. First, the Recovery® Cone continues to be available for distribution and physician use to this day. *See* Ex. B, Modra Dep. Vol. I, at 354:15-17. This is because the FDA gave Bard express permission to continue distribution of the Recovery® Cone subsequent to the issuance of the Warning Letter. *See id.* at

357:20-24. Thus, physicians have had an uninterrupted access to the Recovery® Cone. Any physician who believes he or she needs a Recovery® Cone to remove a Bard IVC Filter may purchase one from Bard. Thus, contrary to the Plaintiffs' statement, patients are not "fac[ing] a significantly more complex removal procedure requiring actual surgery" due to an unavailability of the Recovery® Cone, because it is, in fact, available for use by their physicians. Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 40.

Second, multiple versions of Bard's IVC Filters, including the G2®X, G2® Express, Eclipse®, Meridian®, and Denali® Filters are manufactured with a "hook" at the apex of the filters, which allows them to be retrieved via any number of commercially available snares. Thus, it is not correct to state that the availability or purported unavailability of the Recovery® Cone "affects literally every plaintiff with a lawsuit in the MDL," *id.*, because any plaintiff with a G2®X, G2® Express, Eclipse®, Meridian®, or Denali® Filter has always had the option of having his or her filter removed with a snare, in addition to the Recovery® Cone.

At bottom, the regulatory status of the Recovery® Cone is irrelevant in this litigation. Nonetheless, as described in detail in Bard's portion of the Parties' Joint Report to the Court, Bard has produced a vast amount of information to the Plaintiffs regarding the Recovery® Cone, including all of the core documentation regarding that device. *See* Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 41-42. Bard also produced Mr. Modra as its 30(b)(6) witness regarding the Warning Letter, and he spent substantially all of the second day of his deposition (totaling approximately three hours of deposition testimony) testifying regarding the Recovery® Cone. This discovery regarding the Recovery® Cone provided by Bard in this litigation is more than adequate for this litigation.

D. The FDA's Concerns Regarding Bard's Complaint Handling and MDR Reporting Are Overstated by Plaintiffs

The Plaintiffs spent the vast majority of their first seven hours of the deposition of

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Mr. Modra on issues related to Bard's complaint handling and MDR reporting as identified in the Warning Letter. *See supra* footnote 5. In their portion of the Parties' Joint Report, the Plaintiffs greatly overstate the impact of these issues on this litigation. However, despite the different impression given by the Plaintiffs, the FDA's criticisms (with one narrow exception) did not involve a failure to report adverse events to the FDA. As demonstrated in the chart below, Mr. Modra's testimony makes clear that (a) the FDA's concerns do not affect the integrity or accuracy of Bard's internal trending and rate analyses; (b) the FDA's concerns about Bard's complaint handling and MDR reporting focused on the manner in which Bard documented its decision-making process, not on the decisions themselves; and (c) with the exception of a small number of complaints regarding the failure of the filter to properly deploy (a failure mode not asserted by any of the Plaintiffs in this MDL), the FDA's concerns do not relate to a failure to report a complaint to the FDA. Even for those complaints, FDA has determined that they do not necessarily need to be reported as MDRs.

The Plaintiffs' Exaggerated Claims	**Mr. Modra's Testimony**
Bard allegedly failed to accurately track, categorize, and analyze reports of IVC filter complications.[6] *See* Parties' Joint Report Pursuant to Case Management Order No. 2 [Dkt. No. 451], at p. 29.	Subsequent communications with the FDA have clarified that, in response to the Warning Letter, Bard has actually ***overreported*** instances of "serious injury," when the complaints should have been characterized as "malfunctions." *See* Ex. B,

[6] The primary issue identified by the FDA in the Warning Letter is instances where Bard allegedly should have reported certain events as "serious injuries" as opposed to "malfunctions." *See* Warning Letter, Ex. A, at Item No. 3(b). Those events were all reported to the agency, and details about each incident were set forth in each report. The FDA's criticism solely concerned how Bard classified those events in one section of the MDR form (i.e., checking the "malfunction" box when FDA believed the "serious injury" box should have been checked). However, other sections of the same form included additional information about the events, including where they constituted "adverse events" or were potentially "life threatening."

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The Plaintiffs' Exaggerated Claims	Mr. Modra's Testimony
	Modra Dep. Vol. I, at 221:18-222:2; 227:17-228:16.
Bard allegedly failed to properly report to the FDA hundreds of serious injuries resulting from Bard's IVC filters.[7] *See id.* at 30.	Since the issuance of the Warning Letter, Bard has learned that, even regarding the few deployment complaints that had not been reported, the FDA's concern about MDR reporting was not about an alleged failure to report; instead, FDA wanted more information regarding how Bard documented its decision not to report certain events (e.g., failure of the IVC filter to properly deploy) in the first instance. *See id.* at 225:9-23. With respect to failure to deploy events specifically, FDA does not necessarily require these to be reported as MDRs. *See id.* at 155:10-156:1.
Bard's alleged failure to properly report complaints to the FDA necessarily means that Bard's internal rate information is inaccurate. *See id.*	Bard tracks and trends complaints "regardless of whether it's reportable or not." *Id.* at 110:1-10. Whether an MDR is characterized as a "serious injury" versus a "malfunction" does not affect tracking, trending, or Bard's investigation. Bard's trending is "based on the failure event" (e.g., fracture, migration, perforation), "not

[7] The MDR reporting issue identified by the FDA in the Warning Letter related to instances where a Bard IVC filter allegedly failed to deploy. *See* Warning Letter, Ex. A, at Item No. 7.

The Plaintiffs' Exaggerated Claims	Mr. Modra's Testimony
	just because it's a serious injury or not." *Id.* at 144:21-145:6; *see also id.* at 165:21-166:8; 203:1-7. Indeed, following the Warning Letter, and after a retrospective review of complaint files and MDR reports, Bard recalculated its internal rates and determined that the rates for complications such as fracture, migration, tilt, and perforation ***did not change***. *See* Ex. E, Modra Dep. Vol. II, at 484:24-485:7, 501:19-502:25, 515:8-517:3.
"It is only fair to wonder whether true and accurate reporting of these failures to the FDA would have forced a recall by Bard." *Id.*	Bard's characterization of a complaint (i.e., "serious injury" versus "malfunction" does not affect Bard's risk analysis, which dictates whether remedial actions, including a recall, are needed. *See* Ex. B, Modra Dep. Vol. I, at 164:18-166:8.

The above chart demonstrates that the FDA's concerns regarding Bard's complaint handling and MDR reporting are minor and do not affect Bard's internal trending and rate information, or Bard's risk assessments for its IVC filters. Notwithstanding that these issues raised in the Warning Letter have little impact on this litigation, Bard has provided the Plaintiffs with substantial testimony and documentation regarding Bard's complaint handling and MDR reporting policies and practices. As detailed above, Mr. Modra has given multiple depositions as Bard's 30(b)(6) witness on these topics. Moreover, aside from the voluminous Warning Letter-related documents that Bard has produced to the Plaintiffs -- much of which relates to Bard's actions regarding complaint handling and

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MDR reporting in response to the Warning Letter -- Bard has produced numerous complaint trending documents, as well as relevant standard operating procedures regarding Bard's complaint handling and MDR reporting practices. *See* Index of Complaint Trending Materials, attached as Exhibit "H."

Given that the FDA's concerns about Bard's complaint handling and MDR reporting are vastly overblown by the Plaintiffs, and given the substantial amount of testimony and documents produced by Bard to the Plaintiffs regarding those topics, additional discovery on these issues is not warranted.

III. CONCLUSION

The FDA Warning Letter is not central to the resolution of the issues at stake in this litigation. Instead, it is of marginal importance, at most, and the Plaintiffs vastly overstate the significance of the Warning Letter. In light of the substantial discovery that Bard has produced to date regarding the Warning Letter, the Recovery® Cone, and Bard's complaint handling and MDR reporting practices and procedures, additional discovery (including either depositions or document requests) regarding the Warning Letter is not warranted in this litigation.

DATED this 10th day of February, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.
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